REMARKS

Reconsideration of the Final Rejection is respectfully requested.

Claims 49, 55, 57, 58, 62, 63, 70, 85 and 88-90 have been withdrawn from consideration as being drawn to non-elected species. Reconsideration of the withdrawal from consideration of these claims is respectfully requested. Each of Claims 49, 55, 57, 58, 62, 63, 70, 85 and 88-90 depends on a linking claim, which is generic thereto. If a linking claim is allowed, the Examiner must examine species linked thereto, [MPEP 809.04]. Accordingly, where the Examiner's reconsideration of the linking claims finds them to be patentable, withdrawal of the non-elected species should be considered.

However, the Examiner is hereby authorized to cancel Claims 49, 55, 57, 58, 62, 63, 70, 85 and 88-90 if needed for allowance of the above captioned patent application.

Claims 56, 75 and 84 have been rejected under 35 USC 112 as being indefinite. Claims 56, 75 and 84 have been canceled.

Beneficially, Applicant's invention provides consumers who have a specified discomfort with relief for the discomfort and indications for supplementing nutrition. This enables them to self-regulate their consumption of nutritional supplements while relieving their discomfort. Applicant's invention saves consumers the additional cost, time and storage space needed for purchase and use of the separately enclosed intended discomfort relievers and intended nutritional supplements of the prior art.

LONG FELT NEED SATISFIED COMMERCIALLY

There has been a long felt need for Applicant's invention, which provides a pain reliever indicating both discomfort relief and supplementing nutrition. A new commercial product sold by Bayer (pain reliever and nutritional supplement packaging: EXHIBIT A), satisfies this long felt need for a pain reliever indicating to women both discomfort relief and supplementing nutrition. It was Bayer's newest product for women in May 2002 (EXHIBIT B, Bayer Consumer Care and Tony Raines Race for Women's Health in New Hampshire, page 1 first paragraph). It is the only aspirin product especially for women (EXHIBIT C, New American Heart Association Women's Prevention Guideline Support Aspirin's Benefits, page 3, first paragraph). This new product has the benefits of

Applicant's invention. It enables women to self-regulate their consumption of nutritional supplements while relieving their discomfort. It saves them the additional cost, time and storage space needed for purchase and use of the separately enclosed intended discomfort relievers and intended nutritional supplements of the prior art.

NUTRITIONAL SUPPLEMENT PRODUCT LAW DOES NOT APPLY TO DRUGS

The Examiner states that the law mandates that nutritional supplement products include recommended daily value of vitamin in the food product on the package label, (Advisory Action, paragraph 5 continuation). But, drug products based on the applied pain reliever references, which do not mention food or supplementing diet, are not covered by dietary supplement labeling law [21 CFR 101.36] that mandates that nutritional supplement products include recommended daily value of vitamin in food products on the package labels. The applied discomfort reliever prior art references include antioxidant vitamins as active ingredients of the pain reliever drug. They do not disclose any intention to supplement nutrition. Dietary supplements are products intended to supplement the diet that contain a vitamin, mineral, or herb, Dietary Supplement Health and Education Act of 1994 Section 3 (a)(ff) (1) Nutritional Supplements Association page 3, (EXHIBIT E). So, dietary supplement labeling law [21 CFR 101.36] would not apply to products based on the applied discomfort reliever prior art references, because there is no disclosure in them of food or any intention to supplement the diet.

Thus, food product labeling law does not apply to labeling antioxidant vitamins in drug products. Labeling requirements for drugs 21 CFR 320.1 (b) (EXHIBIT G) are separate from labeling requirements for nutritional supplements. FDA regulates dietary supplements under a different set of regulations than those covering drug products (prescription and over-the-counter), FDA Center for Food Safety and Applied Nutrition, page 1, first paragraph (EXHIBIT F). The applied prior art discomfort reliever references disclose antioxidant vitamins as active ingredients so, they should be listed as active ingredients of the pain reliever in its product labeling (21 CFR 201.66: EXHIBIT H). Neither the labeling requirements for active ingredients for over-the-counter (OTC) drugs, 21 CFR sections 201.60 to 201.66, nor the labeling requirements

for prescription drugs mention percent daily value, nutrition, or dietary supplements, 21 CFR 201.57.

The applied discomfort reliever prior art references disclose pain relief. So labeling for the pain relievers of the applied discomfort reliever prior art references may be required to include pain relief as a principal intended action and/or a use indication for the drug (21 CFR 201.66 (c)(3) and (4): EXHIBIT H). There is no disclosure of supplementing nutrition or percent daily value in the applied discomfort reliever prior art references. So, it would not be obvious for labeling indications for the drug to include supplementing nutrition or percent daily value, as they are neither mandated by drug labeling law or, mentioned or intended in the applied discomfort reliever prior art.

There is no disclosure in Krause of any drug or intention to relieve pain. Drugs are defined by their intended use, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, July 2, 2002, page 1, third paragraph EXHIBIT D. So, drug labeling law does not apply to food products based on Krause, since there is no disclosure in Krause of any drug or any intention to relieve pain.

IT IS NOT OBVIOUS TO PUT INFORMATION ON A LABEL REGARDING UNINTENDED USES OF THE PRODUCT

The Examiner states that just because pain reliever products, which are not nutritional products, do not include nutrition information, does not obviate putting the information on the label, (Advisory Action, paragraph 5 continuation, at "Secondly"). But, putting nutrition information on a pain reliever label is not obvious, because nutrition is an undisclosed and unintended use of the applied prior art pain reliever. It is not obvious to put information regarding undisclosed and unintended uses of the product on its label. Prior art pain reliever products are not nutritional products, because they do not disclose any intention to supplement diet. So it would not be obvious to include nutrition information on their labels.

Putting nutrition information on a pain reliever label is not obvious, because the applied pain reliever prior art teaches away from supplementing nutrition. The applied pain reliever prior art teaches away from supplementing nutrition, and thereby teaches away from putting information on supplementing nutrition on the label. Yeh et al teach that an antioxidant other than a vitamin (A, C or E) may be used (column 2, lines 48-52).

Thus, Yeh et al do not teach that vitamin C (or anything else) is intended to supplement nutrition. So, Yeh et al teach away from supplementing nutrition by teaching that the lack of anything that could function as a nutritional supplement is suitable for its purposes. Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc v Barnes-Hind Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986). Accordingly, no indication of supplementing nutrition would be provided in labeling for antioxidant and/or synergistic vitamin C as part of a pain reliever. Thus, disclosure of antioxidant as an active ingredient of a pharmaceutical essentially teaches away from supplementing nutrition and the invention. So, the prior art teaches away from the invention, which supports a conclusion of nonobviousness, Dow Chemical Co v US,18 USPQ2d 1657, 1662 (US Claims Ct, 1990).

Putting nutrition information on a pain reliever label is not obvious because it is not disclosed by the applied discomfort reliever prior art. Applicant's invention provides indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for the nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. These features are not disclosed by the applied discomfort reliever prior art. Indicating supplementing nutrition for a unit dose of discomfort reliever is a new and additional feature, which is not disclosed in the applied art. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. The rejection does not meaningfully consider all of the limitations of the claims. Accordingly, the claims are not unpatentable over SS Pharmaceutical Tsunoda, Yeh et al and Krause.

INTENDED PURPOSE, NOT FUNCTION, DEFINES BOTH NUTRITIONAL SUPPLEMENT PRODUCTS AND DISCOMFORT RELIEVER PRODUCTS

The Examiner states that the claimed composition functions the same regardless of what is printed on the package and/or such function being taught by the prior art (Advisory Action, paragraph 5 continuation). But, what is printed on the package is determined by what the product is intended to be, and not by undisclosed and unintended functions of its composition. The applied prior art pain reliever references do not disclose supplementing nutrition. So, any supplementing of nutrition is an undisclosed and unintended function of antioxidant vitamins of the applied prior art pain

reliever references. Thus, undisclosed and unintended functions of antioxidant vitamins are not obvious to indicate on pain reliever product labels.

Intended purpose defines both nutritional supplement products and discomfort reliever products, and in so doing defines what is required to be printed on the packaging. Both nutritional supplement products and discomfort reliever products are defined by their intended purpose, which then controls what is required to be printed on the packaging. Drugs are defined by their intended use EXHIBIT D. A dietary supplement is a product intended to supplement the diet that contains a vitamin, mineral, or herb, (EXHIBIT E).

A dietary supplement function is not taught by the applied discomfort reliever prior art. While the applied discomfort reliever prior art references, include antioxidant vitamins, they are not intended to supplement nutrition. There is no disclosure in the applied discomfort reliever prior art references of any intention to supplement the diet. So, any supplementing of nutrition is an undisclosed and unintended function of products based on the applied prior art pain reliever references. Thus, it would not be obvious to indicate supplementing nutrition in labeling or packaging products which are based on the applied prior art pain reliever references.

The Examiner states that there is no data of superior results (Advisory Action, paragraph 5 continuation). Use of Applicant's invention results in superior savings in containers and storage space, superior convenience, and superior ability to self regulate nutritional supplements while alleviating a discomfort. Intended discomfort relievers and intended nutritional supplements of the prior art are separate unit doses in separate containers. They require twice as many containers, and much more storage space than discomfort reliever products indicating both intended discomfort relief and intended supplementing of nutrition in accordance with the invention.

There has been a long felt need for a pain reliever indicating both intended discomfort relief and intended supplementing of nutrition. Applicant's invention provides a superior result by satisfying the long felt need for a pain reliever indicating both intended discomfort relief and intended supplementing of nutrition, particularly for women (EXHIBIT C). Benefits of Applicant's invention, which are not provided by the applied prior art include: a unit dose of discomfort reliever in an enclosure having

indications indicating a percent daily value for nutritional supplement in a unit dose of discomfort reliever.

A practical significance of Applicant's invention, compared to the applied prior art, is that the user has discomfort relief and an additional indication: a percent daily value for the nutritional supplement in each unit dose. With this indication the user has the ability to self regulate consumption of nutritional supplements while alleviating a discomfort. This is a superior result. Also, use of Applicant's invention results in superior convenience and superior savings in storage space and cost. The statute does not require a patentable invention to be superior Demaco Corp v F Von Langsdorff Licensing Ltd. 7 USPQ2d 1222 (Fed. Cir 1988). Applicant's claimed invention results in superior savings in storage space and cost, superior convenience and adds an ability to self regulate nutritional supplements while alleviating a discomfort. Accordingly, the rejection of the claims as being unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is improper. Patentability is shown beyond the requirements of the statute, Demaco.

FOOD LABELING REQUIREMENTS ARE NOT MANDATORY FOR DRUG PRODUCTS

The Examiner states that for a unit dose form of ibuprofen and vitamin C indicating the percent daily value is within the ordinary skill of the art based on mandatory food labeling (Krause), pages 4 and 5 of the Final Rejection. However, pain reliever drug products based on the applied references do not mention food or supplementing diet, so they are not covered by dietary supplement labeling law [21 CFR 101.36] that mandates that nutritional supplement products include recommended daily value of vitamin in food products on the package labels. The applied discomfort reliever prior art references include antioxidant vitamins as active ingredients of the pain reliever drug. They do not disclose any intention to supplement nutrition. Dietary supplements are products intended to supplement the diet that contain a vitamin, mineral, or herb, (EXHIBIT E). So, dietary supplement labeling law [21 CFR 101.36] would not apply to products based on the applied discomfort reliever prior art references, because there is no disclosure in them of food or any intention to supplement the diet.

Thus, food product labeling law does not apply to labeling antioxidant vitamins in drug products. Labeling requirements for drugs are separate from labeling

requirements for nutritional supplements. FDA regulates dietary supplements under a different set of regulations than those covering drug products (prescription and over-the-counter), FDA Center for Food Safety and Applied Nutrition, page 1, first paragraph (EXHIBIT F). The applied prior art discomfort reliever references disclose antioxidant vitamins as active ingredients so, they should be listed as active ingredients of the pain reliever in its product labeling (21 CFR 201.66; EXHIBIT H). Neither the labeling requirements for active ingredients for over-the-counter (OTC) drugs, 21 CFR sections 201.60 to 201.66, nor the labeling requirements for prescription drugs mention percent daily value, nutrition, or dietary supplements, 21 CFR 201.57.

The applied discomfort reliever prior art references do not disclose food or any intention to supplement nutrition. Thus, dietary supplement labeling law 21 CFR 101.36 and Krause are not applicable to labeling products based on the applied discomfort reliever prior art references. While the applied discomfort reliever prior art references include an antioxidant, (which may or may not be vitamin) they do not disclose of any intention to supplement nutrition. SS Pharmaceutical, Tsunoda, and Yeh et al disclose drug medications, and do not disclose food or any intention to supplement diet. Since there is no disclosure in the applied discomfort reliever prior art references of any intention to supplement the diet, dietary supplement labeling law 21 CFR 101.36 and Krause are not applicable to products based on the applied discomfort reliever prior art references. Dietary supplement labeling laws [21 CFR 101.36] do not mention drugs. So, food labeling requirements are not mandatory for drug products. Thus, one of ordinary skill would not be lead or mandated to indicate the percent daily value for antioxidant vitamin C in a unit dose form of ibuprofen and antioxidant vitamin C as active pain reliever ingredients.

Dietary supplement labeling law 21 CFR 101.36 and Krause are not applicable to products based on the applied discomfort reliever prior art references. Dietary supplement labeling laws [21 CFR 101.36] are not for drugs (EXHIBIT F.1). Dietary supplement labeling laws [21 CFR 101.36] would not apply to products based on the applied discomfort reliever prior art references since there is no disclosure in them of any intention to supplement the diet. Accordingly, it would not be obvious from the

applied discomfort reliever prior art references to one of ordinary skill to indicate the percent daily value for a unit dose form of ibuprofen and antioxidant vitamin C.

INDICATION FOR INTENDED USE IS MANDATED BY 21 CFR 201.57

The Examiner states that indication for use is mandated by 21 CFR 201.57, pages 4 and 5 of the Final Rejection. However, drug labeling law [21 CFR 201.57] does not mention percent daily value, nutrition, or dietary supplements. The applied prior art discomfort reliever references disclose antioxidant vitamins as active ingredients, so they may be listed as active ingredients of the pain reliever in its product labeling (21 CFR 201.66: EXHIBIT H). Neither the labeling requirements for active ingredients for over-the-counter (OTC) drugs, 21 CFR sections 201.60 to 201.66, nor the labeling requirements for prescription drugs mention percent daily value, nutrition, or dietary supplements, 21 CFR 201.57.

Labeling requirements for drugs are separate from labeling requirements for nutritional supplements. FDA regulates dietary supplements under a different set of regulations than those covering drug products (prescription and over-the-counter), FDA Center for Food Safety and Applied Nutrition, page 1, first paragraph (EXHIBIT F).

The applied discomfort reliever prior art does not disclose supplementing diet, so no indication is mandated by 21 CFR 201.57 for this undisclosed and unintended use. SS Pharmaceutical, Tsunoda and Yeh et al disclose compositions for pain relief (cold, menstruation and/or periodontal). So, the indications mandated by 21 CFR 201.57(c) may be for pain relief (cold, menstruation and/or periodontal) as an intended use of drug products based on the applied discomfort reliever prior art. Since the applied discomfort reliever prior art does not disclose supplementing diet, no indication is mandated by 21 CFR 201.57 for this undisclosed and unintended use.

The applied prior art pain reliever references disclose including antioxidant and/or synergistic vitamins as part of a pharmaceutical medication (cold, menstruation and/or periodontal). So, the applied prior art pain reliever references disclose compositions which are intended to function to relieve pain, and do not have any disclosure of any intention to supplement the diet. Thus, it would not be obvious to

indicate supplementing nutrition in labeling pain reliever products which are based on the applied prior art pain reliever references.

The applied prior art teaches away from supplementing nutrition, and thereby teaches away from putting information on supplementing nutrition on the label. Yeh et al teach that an antioxidant other than a vitamin (A, C or E) may be used (column 2, lines 48-52). Thus, Yeh et al do not teach that vitamin C (or anything else) is intended to supplement nutrition. So, Yeh et al teach away from supplementing nutrition by teaching that the lack of anything that could function as a nutritional supplement is suitable for its purposes. Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc v Barnes-Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986). Accordingly, no indication of supplementing nutrition would be provided in labeling for antioxidant and/or synergistic vitamin C. Thus, disclosure of antioxidant as an active ingredient of a pharmaceutical essentially teaches away from supplementing nutrition and the invention. So, the prior art teaches away from the invention, which supports a conclusion of nonobviousness, Dow Chemical Co v US,18 USPQ2d 1657, 1662 (US Claims Ct, 1990).

There is no disclosure in Krause of any drug or intention to relieve pain. Drugs are defined by their intended use, EXHIBIT D. So, drug labeling law does not apply to food products based on Krause, since there is no disclosure in Krause of any drug or any intention to relieve pain.

The Examiner states that the law mandates the inclusion of indications, (pages 5, 6, 7 and 8 of the Final Rejection). But, drug products based on the applied pain reliever references, do not mention food or supplementing diet, so they are not covered by dietary supplement labeling law [21 CFR 101.36] that mandates indications in dietary supplement products on the package labels.

The applied discomfort reliever prior art references include antioxidant vitamins as active ingredients of the pain reliever drug. They do not disclose any intention to supplement nutrition. Dietary supplements are products intended to supplement the diet that contain a vitamin, mineral, or herb, (EXHIBIT E). So, dietary supplement labeling law [21 CFR 101.36] would not apply to products based on the applied

discomfort reliever prior art references, because there is no disclosure in them of food or any intention to supplement the diet.

Thus, dietary supplement product labeling law does not apply to labeling antioxidant vitamins in drug products. Labeling requirements for drugs are separate from labeling requirements for nutritional supplements. FDA regulates dietary supplements under a different set of regulations than those covering drug products (prescription and over-the-counter), FDA Center for Food Safety and Applied Nutrition, page 1, first paragraph (EXHIBIT F). The applied prior art discomfort reliever references disclose antioxidant vitamins as active ingredients, so they may be listed as active ingredients of the pain reliever in its product labeling (21 CFR 201.66: EXHIBIT H). Neither the labeling requirements for active ingredients for over-the-counter (OTC) drugs, 21 CFR sections 201.60 to 201.66, nor the labeling requirements for prescription drugs mention percent daily value, nutrition, or dietary supplements, 21 CFR 201.57.

The Examiner states that the ultimate function of the instant composition relies on the active ingredients: ibuprofen and vitamin C (page 8 of the Final Rejection). However, the applied discomfort reliever prior art references do not disclose supplementing nutrition. Thus, any property or function as a nutritional supplement by antioxidant vitamin C is unintended. Intended purpose defines both nutritional supplement products and discomfort reliever products, and in so doing defines what is required to be printed on the packaging. Intended purpose defines both nutritional supplement products and discomfort reliever products, and in so doing defines what is required to be printed on the packaging. Both nutritional supplement products and discomfort reliever products are defined by their intended purpose, which then controls what is required to be printed on the packaging. Drugs are defined by their intended use, EXHIBIT D. A dietary supplement is a product intended to supplement the diet that contains a vitamin, mineral, or herb, (EXHIBIT E). Since any nutrition supplementing function of antioxidant vitamin C in unintended, it would not be obvious to indicate antioxidant vitamin C as supplementing nutrition in labeling a pain reliever product based on the applied prior art discomfort reliever references.

Antioxidant vitamin C is an active ingredient, which is disclosed to function as part of a discomfort reliever, in the applied prior art. It reduces oxidation as see Yeh et al column 2, lines 31-37. There is no disclosure of supplementing nutrition in the applied discomfort reliever prior art. So, it would not be obvious to indicate antioxidant vitamin C as a nutritional supplement in product labeling based on the applied discomfort reliever prior art.

The Examiner states that the identical chemical composition cannot have mutually exclusive properties, and vitamin C functions as nutritional supplement regardless of whether the prior art teaches so, (pages 9 and 10 of the Final Rejection). However, the applied discomfort reliever prior art references do not disclose supplementing nutrition. Thus, any property or function as a nutritional supplement by antioxidant vitamin C is unintended. Intended purpose defines both nutritional supplement products and discomfort reliever products, and in so doing defines what is required to be printed on the packaging. Both nutritional supplement products and discomfort reliever products are defined by their intended purpose, which then controls what is required to be printed on the packaging. Drugs are defined by their intended use, EXHIBIT D. A dietary supplement is a product intended to supplement the diet that contains a vitamin, mineral, or herb, (EXHIBIT E). Since any nutrition supplementing function of antioxidant vitamin C is undisclosed and unintended, it would not be obvious to indicate antioxidant vitamin C as supplementing nutrition in labeling a pain reliever product based on the applied prior art discomfort reliever references.

Also, a product, which is not disclosed or intended to supplement nutrition, is not a dietary supplement under the Dietary Supplement Health and Education Act. A dietary supplement is a product intended to supplement the diet that contains a vitamin, mineral, or herb, (EXHIBIT E). Supplementing nutrition is not disclosed, so it is not intended in the applied discomfort reliever prior art references. Consequently, in labeling for products based thereon it would not be obvious to include indications of any undisclosed and unintended supplementing of nutrition in the applied discomfort reliever prior art references.

Applicant does not claim a chemical composition, but a method of indication for supplementing nutrition. Applicant's invention provides indications indicating

intended nutrition supplementing of the unit dose of a discomfort relieving composition. Antioxidant vitamin C is an active ingredient for discomfort relief, and is not disclosed for any other purpose in the applied discomfort reliever prior art. Thus, since antioxidant vitamin C is an active ingredient for pain relief, and is not intended for supplementing nutrition, it would not be obvious to indicate it for supplementing nutrition.

The Examiner states that it is unclear how the disclosure in Yeh et al of antioxidant vitamin C as part of a pain reliever essentially teaches away from the invention, (page 9 of the Final Rejection). Yeh et al teach that an antioxidant other than a vitamin (A, C or E) may be used (column 2, lines 48-52). Thus, Yeh et al do not teach that vitamin C (or anything else) is provided to supplement nutrition. So, Yeh et al teach away from the invention by teaching that the lack of anything that could function as a nutritional supplement is suitable for its purposes. Accordingly, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic vitamin C as part of a pain reliever.

The Examiner states that a reconstruction is proper if it takes into account only knowledge, which was within the ordinary skill at the time of the invention, and does not include knowledge gleaned from Applicant's disclosure, (page 7 of the Final Rejection). However, the reconstruction is insufficient as it omits features of the invention, when it takes into account only knowledge, which was within the ordinary skill at the time of the invention. More specifically, nowhere in any of the prior art references is there any suggestion to provide a unit dose of discomfort reliever with indications indicating supplementing nutrition.

The Examiner states that the indications are not functionally related to the composition, and that printed material does not patentably distinguish over the prior art, (pages 8-9 of the Final Rejection). Applicant's invention indicates the intended nutrition supplementing function of nutritional supplement in a unit dose of discomfort reliever. Indications indicate the intended functions of supplementing nutrition by a nutritional supplement and relieving discomfort by a discomfort reliever in Applicant's invention. Intended purpose defines both nutritional supplement products and discomfort reliever products, and in so doing defines what is required to be printed on the packaging.

Both nutritional supplement products and discomfort reliever products are defined by their intended purpose, which then controls what is required to be printed on the packaging. Drugs are defined by their intended use, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, July 2, 2002, page 1, third paragraph EXHIBIT D. A dietary supplement is a product intended to supplement the diet that contains a vitamin, mineral, or herb (Dietary Supplement Health and Education Act of 1994 section 3 (a)(ff) (1) Nutritional Supplements Association page 3, (EXHIBIT E). Furthermore, any supplementing of nutrition is an unintended function of antioxidant vitamins of the applied prior art pain reliever references. Unintended functions of antioxidant vitamins are not obvious to indicate on a pain reliever product label.

Indications indicate the intended functions of supplementing nutrition by a nutritional supplement and relieving discomfort by a discomfort reliever in Applicant's invention. The applied prior art pain reliever references disclose compositions which are intended to function to relieve pain. They do not have any disclosure of any intention to supplement the diet. The intended function disclosed for antioxidant vitamin C is as an active ingredient for pain relief (cold, menstruation and/or periodontal). Supplementing nutrition is not disclosed in SS Pharmaceutical (lines 2-3 of the abstract), Tsunoda (lines 1-3 of the abstract) or Yeh et al (column 2, lines 5 and 31-37). The applied prior art pain reliever references disclose including antioxidant and/or synergistic vitamins as part of a pharmaceutical medication (cold, menstruation and/or periodontal). So, the applied prior art pain reliever references disclose compositions which are intended to function to relieve pain, and do not have any disclosure of any intention to supplement the diet. Thus, it would not be obvious to indicate supplementing nutrition in labeling products which are based on the applied prior art pain reliever references.

Any indication of supplementing nutrition would be for an unintended function in labeling products based on the applied prior art pain reliever references. The applied discomfort reliever prior art references, include antioxidant vitamins. The antioxidant vitamins are only disclosed as being active ingredients of the discomfort reliever. The antioxidant vitamins are not disclosed as being intended to supplement nutrition. There is no disclosure in the applied

discomfort reliever prior art references of food or supplementing diet. Thus, any indication of supplementing nutrition would be for an unintended function in labeling products based on the applied prior art pain reliever references.

The fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination, Application of Miller 164 USPQ 46 (CCPA 1969). Applicant's claimed method combines indications indicating supplementing nutrition with a unit dose of discomfort reliever in an enclosure. Thus, the claim recitation of indications indicating supplementing nutrition combined with a unit dose of discomfort reliever in an enclosure may not be ignored, Application of Miller.

Additionally, the Court stated that one gives printed matter patentable weight if it is functionally related to the substrate, and the court found that printed matter (numbers) did bear a presumptively new and unobvious functional relation to the substrate, In re Gulack 703 F2d 1381, 217 USPQ 401 (CAFC, 1983). Applicant's invention provides indications indicating the intended nutrition supplementing function of the unit dose of discomfort relieving composition. The prior art does not disclose this function. So, indications indicating supplementing nutrition should be given patentable weight as they are indication of a nonobvious intended function of the unit dose of the discomfort reliever in the enclosure, which provides superior results.

Any supplementing of nutrition is unintended in the applied pain reliever prior art. Furthermore, Applicant's invention educates the user of the nutrition supplementing function of the unit dose of discomfort reliever. These nonobvious features form a basis for patentability In re Gulack. The court has cautioned against liberal use of printed matter rejections, In re Lowry 32 F3d 1579, 32 USPQ 2d 1031 (CAFC, 1994). As part of its burden to establish a prima facie case of obviousness, the burden of establishing the absence of a novel, nonobvious functional relationship rests with the PTO. The PTO must establish this within the context of the entire claims, In re Lowry. The Examiner has not established the absence of a novel, nonobvious functional relationship

between indications indicating intended supplementing of nutrition and a unit dose of nutritional supplement and discomfort reliever in an enclosure.

The Examiner states that one cannot show nonobviousness by attacking references individually where the rejection is based on a combination of references, In re Keller, 642 F.2d 413, 425, 208 USPQ 871 881 (CCPA 1981) and In re Merck & Co. 231 USPQ 375, 380 (CAFC, 1986) (page 6 of the Final Rejection). While the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art, In re Keller. The combination of references is improper because it lacks a basis for combining the teachings of the references, In re Semaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983).

LACK OF ANY TEACHING FOR THE COMBINATION OF REFERENCES

Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 have been rejected under 35 USC 103 as being unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al in view of Krause. Beneficially, Applicant's invention provides a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. For example, the enclosure may have indications indicating a nutritional supplement for supplementing nutrition, a percent of a daily value for a nutritional supplement and/or instructions for consuming the unit dose for supplementing nutrition. A proper combination of references requires a teaching in the references to suggest the combination thereof, In re Semaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983), and cannot be based on forbidden hindsight, In re Rouffet 47 USPQ2d 1453, 1458 (CAFC, 1998). SS Pharmaceutical, and Tsunoda, and Yeh et al disclose pharmaceutical medication (cold, menstruation and/or periodontal).

The Examiner states that Krause discloses food product labeling. However, pharmaceutical medication (cold, menstruation and/or periodontal) is not disclosed by Krause. Neither food, food product labeling, nutrition nor supplementing nutrition is disclosed by SS Pharmaceutical, Tsunoda, or Yeh et al. There is no teaching in SS Pharmaceutical, Tsunoda, Yeh et al or Krause to suggest the combination thereof to provide the method claimed by Applicant. This

lack of a showing of motivation for combining references cited in the rejection is clear error, In re Sernaker, and is based on forbidden hindsight, In re Rouffet. Accordingly, the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause is clearly improper.

THE COMBINATION OF REFERENCES IS A HINDSIGHT RECONSTRUCTION OF APPELLANT'S INVENTION

A problem with the rejection is that nowhere in any reference is there any suggestion to provide a unit dose of discomfort reliever (with or without an antioxidant and synergistic part of the discomfort reliever) with indications indicating supplementing nutrition. Beneficially, Applicant's invention provides a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. For example, the enclosure may have indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for a nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. To say that this would have been obvious is to resort to impermissible hindsight, In re Marshall 198 USPQ 344 at 346-347 (CCPA, 1978).

Cold medication in SS Pharmaceutical, menstruation medication in Tsunoda, periodontal medication in Yeh et al and food labeling in Krause are isolated disclosures. One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention, In re Fine, 837 F2d 1071, 1075, 5 USPQ 2d 1598, 1600 (Fed. Cir. 1988). The Examiner has picked and chosen among isolated disclosures in the prior art for medication, and isolated disclosures in the prior art for food labeling. It is legal error to use the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann, 901 F2d 823, 828, 15 USPQ 2d 1738, 1742 (Fed. Cir 1990). In constructing the rejection the Examiner combines SS Pharmaceutical, Tsunoda, Yeh et al and Krause without any teaching in the references for the combination thereof. The Examiner has made legally erroneous use of the inventor's patent specification teaching of both a novel and

nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann. So, the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause of the rejection is legal error.

SUPERIOR RESULTS

Applicant's invention indicates intended supplementing of nutrition in a discomfort reliever, which results in superior savings in storage space and cost, superior convenience and adds the ability to self regulate nutritional supplements while alleviating a discomfort. There has been a long felt need for Applicant's invention, which provides a pain reliever indicating both discomfort relief and supplementing nutrition. Applicant's invention enables users to self-regulate their consumption of nutritional supplements while relieving their discomfort. It saves them the additional cost, time and storage space needed for purchase and use of the separately enclosed intended discomfort relievers and intended nutritional supplements of the prior art.

Benefits of Applicant's invention, which are not provided by the applied prior art include: a unit dose of discomfort reliever in an enclosure having indications indicating a percent daily value for nutritional supplement in a unit dose of discomfort reliever. A practical significance of Applicant's invention, compared to the applied prior art, is that the user has discomfort relief and an additional indication: a percent daily value for the nutritional supplement in each unit dose. With this indication the user has the ability to self regulate consumption of nutritional supplements while alleviating a discomfort. This is a superior result. Also, since the invention requires only half as many unit doses in only half as many containers as the prior art, use of Applicant's invention results in superior convenience and superior savings in storage space and cost. The statute does not require a patentable invention to be superior Demaco Corp v F Von Langsdorff Licensing Ltd. 7 USPQ2d 1222 (Fed. Cir 1988). Thus, Applicant's claimed invention provides superior results. Accordingly, the rejection of the claims as being unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is improper. Patentability is shown beyond the requirements of the statute, Demaco.

The Examiner states that the indications that provide the superior results are expected because the law requires them (page 3 of the Final Rejection). While dietary supplement labeling law provides for indications of dietary supplements, antioxidant vitamin C is not mentioned (or intended) to supplement diet in the applied prior art discomfort reliever references. Dietary supplements are products intended to supplement the diet that contain a vitamin, mineral, or herb, (EXHIBIT E). The applied discomfort reliever prior art references include antioxidant vitamins as active ingredients of the pain reliever drug. They do not disclose food, or any intention to supplement nutrition. Thus, products based on the applied prior art discomfort reliever references do not include intended dietary supplements. So, dietary supplement labeling law would not apply to these products, because there is no disclosure in them of food or any intention to supplement the diet. Thus, the mandates of dietary supplement labeling law do not apply to package labels for products based on the applied prior art discomfort reliever references.

The applied prior art discomfort reliever references disclose antioxidant vitamins as active ingredients, so they may be listed as active ingredients of the pain reliever in its product labeling (21 CFR 201.66: EXHIBIT H). Neither the labeling requirements for active ingredients for over-the-counter (OTC) drugs, 21 CFR sections 201.60 to 201.66, nor the labeling requirements for prescription drugs mention percent daily value, nutrition, or dietary supplements, 21 CFR 201.57.

SS Pharmaceutical, Tsunoda, and Yeh et al disclose drug medications, and do not disclose food or any intention to supplement diet. Only drug products would be based on the disclosures of ibuprofen and antioxidant vitamin C in the applied discomfort reliever prior art references. While the applied discomfort reliever prior art references include an antioxidant, (which may or may not be vitamin) they do not disclose of any intention to supplement nutrition. Since there is no disclosure in the applied discomfort reliever prior art references of any intention to supplement the diet, dietary supplement labeling law (Krause) is not applicable to products based on the applied discomfort reliever prior art references. Thus, the indications that support the

superior results are not expected because they are not required by law. So, it would not be obvious to one of ordinary skill to include such indications.

The applied discomfort reliever prior art does not disclose supplementing diet, so no indication is mandated by 21 CFR 201.57 for this undisclosed and unintended use. SS Pharmaceutical, Tsunoda and Yeh et al disclose compositions for pain relief (cold, menstruation and/or periodontal). So, the indications mandated by 21 CFR 201.57(c) may be for pain relief (cold, menstruation and/or periodontal) as an intended use of drug products based on the applied discomfort reliever prior art. Since the applied discomfort reliever prior art does not disclose supplementing diet, no indication is mandated by 21 CFR 201.57 for this undisclosed and unintended use. Thus, it would not be obvious to indicate supplementing nutrition in labeling pain reliever products which are based on the applied prior art pain reliever references.

The applied prior art teaches away from supplementing nutrition, and thereby teaches away from putting information on supplementing nutrition on the label. Yeh et al teach that an antioxidant other than a vitamin (A, C or E) may be used (column 2, lines 48-52). Thus, Yeh et al do not teach that vitamin C (or anything else) is intended to supplement nutrition. So, Yeh et al teach away from supplementing nutrition by teaching that the lack of anything that could function as a nutritional supplement is suitable for its purposes. Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc v Barnes-Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986). Accordingly, no indication of supplementing nutrition would be provided in labeling for antioxidant and/or synergistic vitamin C. Thus, disclosure of antioxidant as an active ingredient of a pharmaceutical essentially teaches away from supplementing nutrition and the invention. So, the prior art teaches away from the invention, which supports a conclusion of nonobviousness, Dow Chemical Co v US,18 USPQ2d 1657, 1662 (US Claims Ct, 1990).

There is no disclosure in Krause of any drug or intention to relieve pain. Drugs are defined by their intended use, EXHIBIT D. So, drug labeling law does not apply to food products based on Krause, since there is no disclosure in Krause of any drug or any intention to relieve pain.

Dietary supplement labeling law 21 CFR 101.36 and Krause are not applicable to products based on the applied discomfort reliever prior art references. Dietary supplement labeling laws [21 CFR 101.36] are not for drugs (EXHIBIT F.1). Dietary supplement labeling laws [21 CFR 101.36] would not apply to products based on the applied discomfort reliever prior art references, since there is no disclosure in them of any intention to supplement the diet. Thus, the indications that support the superior results are not expected because they are not required by law. Accordingly, it would not be obvious to one of ordinary skill to indicate supplementing nutrition or a percent daily value for a unit dose form of ibuprofen and antioxidant vitamin C from the applied discomfort reliever prior art references.

THE APPLIED REFERENCES TEACH AWAY FROM THE INVENTION

The Examiner states that it is unclear how the disclosure in Yeh et al of antioxidant and/or synergistic vitamin C as part of a pain reliever essentially teaches away from the invention, (page 9 of the Final Rejection). Yeh et al teach that an antioxidant other than a vitamin (A, C or E) may be used (column 2, lines 48-52). Thus, Yeh et al do not teach that vitamin C (or anything else) is intended to supplement nutrition. So, Yeh et al teach away from the invention by teaching that the lack of anything that could function as a nutritional supplement is suitable for its purposes. Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc v Barnes-Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986). Accordingly, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic vitamin C as part of a pain reliever. Thus, disclosure of antioxidant as an active ingredient of a pharmaceutical essentially teaches away from the invention. So, the prior art teaches away from the invention, which supports a conclusion of nonobviousness. Dow Chemical Co v US,18 USPQ2d 1657, 1662 (US Claims Ct, 1990).

Furthermore, in general a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Applicant. In re Gurley 27 F3d 551; 31 USPQ 2d 1130, 1132 (CAFC, 1994). The applied prior art references teach away, as their

disclosures of antioxidants are unlikely to be productive of the result of indications indicating supplementing nutrition sought by Applicant's claimed invention, In re Gurley. Accordingly, claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 are not prima facie obviousness over the combination of SS Pharmaceutical, Tsunoda, Yeh et al and Krause.

THE APPLIED REFERENCES DO NOT DISCLOSE THE FEATURES OF THE CLAIMED INVENTION OR ANY BENEFIT FROM THE USE THEREOF

The court has held that the absence from the applied references of an explicit requirement of the claims makes the rejection improper, In re Evanega 4 USPQ 2nd 1249 (CAFC, 1987). All of the claims explicitly require a method of providing a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition. Beneficially, Applicant's invention provides, for example, indications indicating a percent of a daily value for nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. The applied prior art does not disclose a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition.

The applied medication prior art does not disclose or teach including any amount of antioxidant and/or synergistic vitamins beyond that, which is part of a pharmaceutical medication (cold, menstruation and/or periodontal). Nor does the applied medication prior art disclose or teach any amount of any antioxidant and/or synergistic vitamin for nutrition. Additionally, the applied medication prior art does not disclose a discomfort reliever in an enclosure having indications indicating supplementing nutrition. The applied medication prior art does not disclose indications indicating a daily value for supplementing nutrition for any amount of the antioxidant and/or the synergistic portion of the pharmaceutical. In the applied medication prior art, pharmaceutical antioxidant and/or synergistic vitamins are not disclosed as being provided to supplement nutrition. Nor are they disclosed as providing a daily value for a nutritional supplement. So, one of ordinary skill in the pharmaceutical art would not indicate an antioxidant and/or synergistic vitamin as being provided for supplementing nutrition. Thus, the

applied prior art references do not disclose or teach a method of enclosing a unit dose of a discomfort reliever in an enclosure having indications indicating supplementing nutrition, as claimed by Appellant. These explicit requirements of the claims are not disclosed by SS Pharmaceutical, Tsunoda, Yeh et al or Krause. SS Pharmaceutical (lines 2-3 of the abstract), Tsunoda (lines 1-3 of the abstract) and Yeh et al (column 2, lines [illegible] and 31-37) disclose including antioxidant and/or synergistic vitamins as part of a pharmaceutical medication (cold, menstruation and/or periodontal). Krause does not disclose a discomfort reliever. The absence from all of the applied references of these explicit requirements of the claims makes the rejection erroneous and improper, In re Evanega. Accordingly, the claims are not unpatentable under 35 USC 103 over SS Pharmaceutical in view of Tsunoda, Yeh et al and Krause.

Additionally, the applied prior art does not provide the benefits of the invention. Beneficially, the invention provides the user with an indication of a percent of a daily value for nutritional supplement in the unit dose. With this indication the user has the ability to self regulate consumption of nutritional supplements while alleviating a discomfort.

ALL THE LIMITATIONS OF A CLAIM MUST BE CONSIDERED MEANINGFUL

All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. v Westinghouse Elec. Corp. 3 USPQ2d 1321, 1324-25 (Fed. Cir, 1987). Applicant's claims require a method of providing a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. Beneficially, Applicant's invention provides, for example, indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for the nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. These features are not disclosed by the applied discomfort reliever prior art. Indicating supplementing nutrition for a unit dose of discomfort reliever is a new and additional feature, which is not disclosed in the applied art. All of the limitations of a claim must be considered meaningful, Perkin – Elmer Corp. The rejection does not

meaningfully consider all of the limitations of the claims. Accordingly, the claims are not unpatentable over SS Pharmaceutical Tsunoda, Yeh et al and Krause.

Krause discloses labeling for food (see page 277, last paragraph). Food contains protein, fat, carbohydrate, and has an energy value, see Krause page 279, right column, first paragraph. The disclosure in Krause of food, protein, fat, or carbohydrate, and energy value is not a basis for relieving a discomfort, as is required by Applicant's claims. The applied medication prior art does not disclose food, protein, fat, carbohydrate, or energy values. So, there is no basis for combining it with Krause. The applied medication prior art discloses pharmaceuticals having antioxidant and/or synergistic vitamins, as part of the pharmaceuticals. Any optimization of these antioxidant and/or synergistic vitamins, as part of the pharmaceuticals disclosed by the applied medication prior art, would be for their antioxidant and/or synergistic functions in the pharmaceuticals. By contrast, Applicant's invention provides, for example, indications indicating a nutritional supplement for supplementing nutrition; a percent of a daily value for the nutritional supplement in the unit dose and/or instructions for consuming the unit dose for supplementing nutrition. The rejection is improper as it does not meaningfully consider all of the limitations of the claims, Perkin – Elmer. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is erroneous.

The applied medication prior art discloses pharmaceuticals, which include antioxidant and/or synergistic vitamins, as see Yeh et al, column 2, lines 5 and 31-37. These antioxidant and/or synergistic vitamin(s) are disclosed as part of the pharmaceutical. Disclosure of an antioxidant and/or a synergistic vitamin as part of a pharmaceutical is not a basis for indicating a nutritional supplement is being provided to supplement nutrition. The rejection is improper as it does not meaningfully consider all of the limitations of the claims, Perkin – Elmer. Accordingly, the rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69,71-84, 86-87 and 91-94 as unpatentable over SS Pharmaceutical, Tsunoda, Yeh et al and Krause is erroneous.

TOPICAL TREATMENTS

Yeh et al discloses topical treatment of periodontal disease with a synergistic anti-inflammatory and antioxidant, as see column 1, lines 6-7 and column 2, lines 1-12. Yeh et al does not disclose supplementing nutrition or indicating a daily value for a nutritional supplement. Oral dosage form orally consumable material is not disclosed by Yeh et al. Accordingly, the claims are not unpatentable over SS Pharmaceutical, Tsuboda, Yeh et al and Krause.

The claims are believed to be allowable. Such action is respectfully requested.

Respectfully submitted,

Dale Lovercheck

DALE R. LOVERCHECK April 1, 2004
Patent Attorney Reg. No. 28638
Telephone number: (610) 872-5150